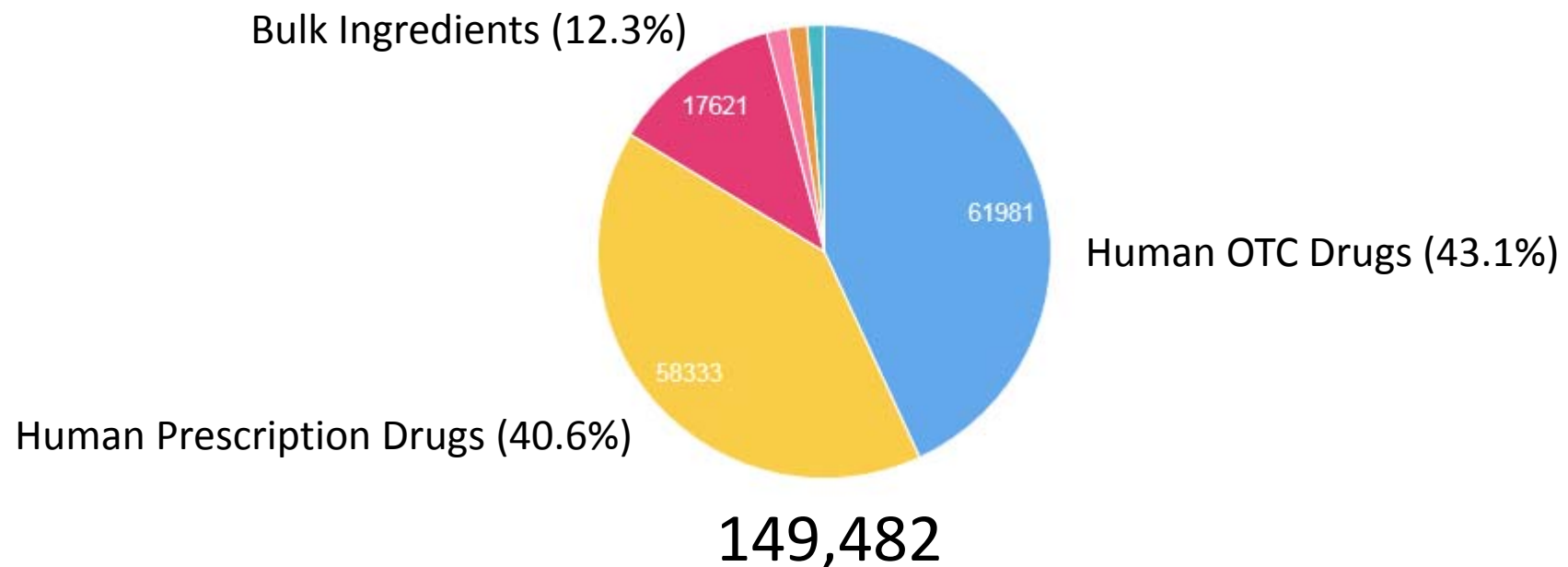


21 CFR 207 Updates

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DailyMed/RxNorm Jamboree
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Do you know how many drugs are in U.S. commercial distribution?





Registration and listing

Part 207 of Title 21 of Code of Federal Regulations (CFR) includes drug registrations and listing requirements.

- New revised rule published in August 2016
- Effective date of November 2016
- Most compliance dates set for November 2017



New and updated requirements

- NDC reservation
- Drug salvagers drug listing
- No Change Certification for drug listing files
- Inclusion of inactive ingredients on the listing SPL
- Inclusion of DMF for unfinished drugs

Update to industry



NDC reservation

Inclusion of lot number for CDER salvaged drugs



Update to industry

- No change certification
 - New SPL Document Type
 - BLANKET NO CHANGES CERTIFICATION OF PRODUCT LISTING --- LOINC Code 86445-4
 - Using NDCs for a blanket certification
 - Certification period starting in October 2017
- Inclusion of inactive ingredients on the listing SPL
 - Available for use
 - Confidentiality option available



Update to industry

- Inclusion of DMF for unfinished drugs
 - Available for use
- Identifying sample package sizes on listing SPLs
 - Available for use
 - Published but not identified in the packaging section of the SPL on DailyMed
 - Will be soon published and identified on the NDC Directory



Some new SPL terminology and validation rules:

- Recovery to Salvage
- Document Type: Drugs for Further Processing
- “Exclusively Manufactured for Private Label Distributors” marketing categories switched to “Manufactured Under Contract”



Some new SPL terminology and validation rules:

- Adding flavor to the new NDC requirement validations
- Adding active ingredient and route of administration validations to NDA and ANDA products (OTC and Rx)



Compliance Update

- Untitled and warning letters
- Removal statement on the NDC Directory:

Current through September 01, 2017

Records marked with (E): This information was removed from publication, because FDA has found inaccuracy in the data submitted by the firm. Data will be released for publication once complete and accurate information is submitted to FDA

Acetaminophen and Codeine Phosphate (E)	██████ 0216-0					██████ ██████ ██████ ██████						N/A			N/A	N/A
Acetazolamide (E)	██████ 0279-0					██████ ██████ ██████ ██████						N/A			N/A	N/A
Adipex-P (E)	██████ 0284-0					██████ ██████ ██████ ██████						N/A			N/A	N/A



Compliance Update

- Listing records with open compliance cases cannot be certified.
- Data removal from DailyMed
 - One firm's had over 2,000 drug listing files removed in June 2017
- Data removal from NSDE files might affect reimbursement.



What will be next

- Revising the guidance document: Providing Regulatory Submissions in Electronic Format – Drug Establishment Registration and Drug Listing
- DRLS/CDER Direct Workshop:

October 5, 2017 9:00am - 5:00pm Eastern

Tommy Douglas Conference Center

10000 New Hampshire Ave, Silver Spring, MD 20903

Registration link:

https://events-na12.adobeconnect.com/content/connect/c1/1315899612/en/events/event/shared/1739981987/event_registration.html?sco-id=1741444539&_charset=utf-8

What will the U.S. drug listing profile look like next year?

Questions



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